Statement of quality

INTEGRA

Product name: All GRIPTIPS®, CLEAR ADVANTAGE® reservoirs, PIPETBOY/VACUSIP filters and INTEGRA serological pipetes

Our commitment to customers:

INTEGRA consumables are produced from virgin materials using precise and consistent manufacturing techniques that ensure quality and excellent performance. We strive to exceed our customers' expectations and encourage continuous feedback. The consumables are manufactured in accordance to ISO 9001.

Our product lots are traceable down to the corresponding raw materials used and date produced.

Our manufacturing process incorporates consistent in-process inspection throughout all phases of fabrication and assembly. All consumables are produced in a cleanroom setting to ensure purity and cleanliness. INTEGRA consumables produced under these strict conditions are contaminant free and consistent from lot-to-lot.

Sterility[1¦2¦3]: These products are manufactured, packaged and sterilized under controlled conditions and are considered sterile until opened and not having exceeded the expiry date. Sterile products have been released compliant with ISO 11137[1¦2] or ISO 11135[3]. The products meet a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

Pyrogen testing[1]: These products are regularly tested for endotoxins. Technicians certified to USP/FDA guidelines for medical devices perform the *Limulus amoebocyte* lysate (LAL) test according to USP 31 (United States Pharmacopeia) guidelines using the LAL gel clot procedure. The endotoxin acceptance level is <0.06 EU/ml.

PCR inhibitors[1]: These products are regularly tested for PCR-inhibiting contaminants.

TSE/BSE statement[1¦2¦3]: The raw materials used in the manufacturing of these products are free of ingredients of animal origin and are therefore deemed to be free of TSE/BSE-causing agents.

Ribonuclease (RNase) / Deoxyribonuclease (DNase)[1¦2]: These products are regularly tested for DNase and RNase and are free of any detectable DNA or RNA degradation.

Human DNA[1¦2]: These products are regularly tested for detectable genomic DNA.

Cytotoxicity testing[2¦3]: The test is conducted to qualify that all materials use USP and / or ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

Graduation accuracy[2]: Random samples of products with graduation markings are taken from each lot to ensure that the markings comply with our specification of ±2% at full scale.

1: applies to GRIPTIPS and CLEAR ADVANTAGE reservoirs
2: applies to INTEGRA serological pipetes
3: applies to PIPETBOY/VACUSIP filters

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